DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 22, 2015

BH Medical Products Co., Ltd.
C/O Ms. Di Wu
MEDevice Union, Ltd.
Regulatory Affairs Specialist
12F Weiya Building, No. 29 Suzhou Street
Haidian District
Beijing 100080

Re: K133070
Trade/Device Name: Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G
Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: II
Product Code: FXX
Dated: May 17, 2015
Received: May 22, 2015

Dear Ms. Wu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133070

Device Name

Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G
Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G.

Indications for Use *(Describe)*

The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Summary Prepared Date: 06/12/2015

Submission Sponsor (Manufacturer):

BH Medical Products Co., Ltd.
No.90 Zhangjia Industrial Area, Xiling
Changzhou , Jiangsu, China 213024

Submission Correspondent (Agent):

Di Wu
Regulatory Affairs Specialist

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Trade/Device Name:
Surgical Face Mask, Ear Loops, Model
101B, 101G, 136B, 136G, 137B, 137G

Surgical Face Mask, Tie-on, Model
145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G, 151B, 151G.

Device Class: II
Classification Name: Mask, Surgical
Regulation Number: 21 CFR 878.4040
Product Code: FXX
Review Panel: General & Plastic Surgery
Predicate Device:

- K131879
  KIMBERLY-CLARK CORP
  KIMBERLY-CLARK, KC300 Mask

Device Description:

The surgical face masks are pleated 3 plys single use, disposable masks.
Inner layers and outer layers are made of spun-bond polypropylene.
Middle layer is made of melt blown polypropylene filter.
Earloops are Knitted Elastic loops (not made with natural rubber latex).
Tieon is made of spun-bond polypropylene.
The nose piece is a malleable aluminum wire.

Over the counter use: Yes
Duration and type of contact: Direct contact, less than 24 hours, skin contact
Single use disposable device: Yes
Sterile: No

Intended Use:

The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.

Comparison to Predicate Devices:

The surgical face masks are essentially the same as or similar to the predicate device in terms of the intended use, design and construction, performance characteristics.

Descriptive Information	Proposed Device	Predicate Device	SE
510(k) Number	K133070	K131879	N/A
Manufacturer	BH Medical Products Co., Ltd	Kimberly-Clark Corp	N/A
Proprietary or Model Name	Surgical Face Mask, Ear Loops, Model 101B, 101G, 136B, 136G, 137B, 137G Surgical Face Mask, Tie-on, Model 145B, 145G, 143B, 143G, 138B, 138G, 142B, 142G,	Face Masks, KC300	N/A

	151B, 151G.				
Indication for Use	The surgical face masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These facemasks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.			The Kimberly-Clark, Face Mask(s) is intended to.be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark, face mask(s) is a single use, disposable device(s), provided non-sterile.	Same
ASTM Level	1	2	3	3	similar
Design feature	Tie-on/ earloop	Tie-on/ earloop	Tie-on/ earloop	Tie-on/earloop	same
Mask styles	3 flat pleated			4 flat pleated	similar
Product Performance Specifications	Meet ASTM F1862-07			Meet ASTM F1862-07	similar
	Meet ASTM F2101-07			Meet ASTM F2101-07	similar
	Meet ASTM F2299-03			Meet ASTM F2299-03	similar
	Meet MIL-M-36954C			Meet MIL-M-36954C	similar
	Meet 16 CFR Part 1610			Meet 16 CFR Part 1610	similar
16 CFR Part 1610 Flammability class	Class 1			Class 1	similar
Single Use	Yes			Yes	same
Disposable	Yes			Yes	same
Non-sterile	Yes			Yes	same
Outer Facing Layer	Spunbond Polypropylene			Polyethylene/Polyester, with ink print	same
Middle Layer	Meltblown Polypropylene			Spunbond Middle Layer: Polypropylene spunbond Meltblown Middle Layer: Polypropylene Meltblown	similar
Inner Facing Layer	Spunbond Polypropylene			Polyethylene/Polyester	similar
Binding	Spunbond Polypropylene			Polyester spunlace, or	similar

		Polypropylene spunbond	
Nosepiece	Aluminum Wire	Unknown	same
Earloop	Polyester	Polyester/Lycra Knitted	same
Tieon	Spunbond Polypropylene	Polypropylene spunbond	similar
Offered as fog free	-	Yes	-
Offered with Visor	-	Yes	-
Color	Blue, Green	Unknown	similar
Dimension (width)	6.8"+/-0.25",	6.5"+/-0.75"	similar
Dimension (length)	3.5"+/-0.25" 4.2"+/-0.25"	4.5"+/-0.75"	similar
Over the counter use	Yes	Yes	Same
Biocompatibility	Non-cytotoxic, Non-sensitizer, non-irritant	Non-cytotoxic, Non-sensitizing, non-irritating	Same

Discussion of Non-Clinical Tests Performed:

The performance tests of surgical face masks were conducted.

ASTM F2299-03 Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

ASTM F1862-07 Standard Test Method For Resistance Of Medical Face Masks To Penetration By Synthetic Blood (Horizontal Projection Of Fixed Volume At A Known Velocity)

ASTM F2101-07 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (Bfe) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus. (General Plastic Surgery/General Hospital)

MIL-M-36954C Military Specification - Mask, Surgical, Disposable

16 CFR Part 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES

ISO 10993-1: 2009, Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process. (Biocompatibility)

ISO 10993-5: 2009, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

ISO 10993-10: 2010, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

Therefore, we conclude that the surgical face masks are both safe and effective for its intended use.

Discussion of Clinical Tests Performed:

None

Conclusion:

The device is as safe and as effective for their intended use as the predicate device.